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| 10/538,427 | 04/04/2006 | Hugh Scmple Munro | ETH5029USPCT | 3197 |

27777 7590 10/29/2007
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| EXAMINER |
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JACKSON, BRANDON LEE

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| ART UNIT | PAPER NUMBER |
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3772

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10/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,427

Applicant(s)

MUNRO ET AL.

Examiner

Brandon Jackson

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/10/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed 6/10/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

Claim Objections

Claim 5 is objected to because of the following informalities: "adhesive" should be "adhered." Appropriate correction is required.

Claim 16 is objected to because of the following informalities: "releasable cover" should be "removable cover". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 recites the limitation "the outward facing surface" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 8 recites the limitation "the sheet" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the hydrogel composition layer" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the layer of hydrogel material" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 recites the limitation "the hydrogel sheet" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "optionally" fails to positively claim the limitations

following the term; therefore, the limitations will be treated as inessential to the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, 13-15, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Webster (US Patent 4,541,426). Webster discloses a wound dressing comprising a first portion (2) comprising a flexible plasticized hydrophilic polymer matrix with an cellular internal structure (col. 2, lines 49-64), a second portion (1) comprising a flexible plasticized hydrophilic (col. 2, lines 4-6) matrix that is relatively continuous (col. 5, lines 42-44), and apertures (4) providing fluid communication (fig. 1) between the first and second portions (2, 1). The hydrogel composition (2, 1) is adhered to the skin, wherein the second portion (1) has a wound facing surface that contacts the skin (col. 5, lines 10-12). The wound dressing further comprises an absorbent layer (6) for receiving fluid through the hydrogel composition (2, 1) and comprising a layer of hydrophilic foam (col. 7, lines 54-56), a removable cover sheet (3) to cover the wound facing surface of the hydrogel composition (2, 1). The wound dressing is sterile and packaged in a microorganism0impermeable container (col. 5, lines 21-23). The hydrogel composition

Art Unit: 3772

(2, 1) comprises a synthetic polymer; therefore, it inherently must have been formed through the polymerization of at least one monomer. The method step is inherent to the usage of the wound dressing.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webster (US Patent 4,541,426). Webster substantially discloses the claimed invention; see rejection to claim 1 above. Webster further discloses the first portion comprising a porous internal structure and the second portion that is relatively continuous, not as porous. Therefore, the ratio of cell void between the first portion and the second portion that is greater than 1:1. The 1:3 ratio provides no advantage, is not used for a particular purpose, and does not solve a stated problem. The Webster device would function

Art Unit: 3772

equally as well with a 1:3 ratio or greater. Therefore, it is a mere design choice and would be obvious to one of ordinary skill in the art at the time of the invention to modify the ratio of sell voids to be greater than 1:3.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webster (US Patent 4,541,426) in view of Takahashi et al. (US Patent 5,972,452). Webster substantially discloses the claimed invention; see rejection to claim 1 above. Webster fails to disclose the apertures of the second portion continuing into the first portion without penetrating it entirely. However, Takahashi teaches a wound dressing (10) comprising apertures (24) that penetrate a layer (20) without fully penetrating the layer (20). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify the apertures in the first portion to be varying lengths that do not fully penetrate the layer, as taught by Takahashi, in order to vary the flexibility of the layer as desired by the user.

Claims 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster (US Patent 4,541,426) in view of Nielsen (US Patent Application Publication 2003/0153860). Webster substantially discloses the claimed invention, see rejection to claim 1 above, and a wound dressing having a substantially uniform thickness (fig. 3). Webster fails to disclose an absorption capacity between 30 and 10,000 %, a water uptake rate of at least 2 micro-L/s, a thickness between about 0.5 to 10 mm, a substantially liquid-impermeable backing layer, and adhesive on the backing layer. However, Nielsen teaches a wound dressing (fig. 1) comprising a substantially liquid-impervious (par. 0054) backing layer (1) covering an absorbent layer (2) and whose

Art Unit: 3772

edges extend beyond the absorbent layer (2), an adhesive layer (3) disposed on the backing layer (1) all the way to the edges of the backing layer (1) and on a portion of the absorbent layer (2) while extending beyond the absorbent layer (2), rapid fluid uptake (par. 0072), and high absorption capacity (par. 0029). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Webster device to have a backing layer and adhesive that extend beyond the absorbent pad, as taught by Webster, in order to trap liquid within the absorbent layer and adhesive only on a portion of the hydrogel composition in order to facilitate rapid fluid uptake. The absorption capacity between 30 and 10,000%, fluid uptake rate of at least 2 micro-L/2, and thickness between about 0.5 to 10mm provides no advantage, is not used for a particular purpose, and does not solve a stated problem. The Webster/Nielsen device would function equally as well with an absorption capacity between 30 and 10,000%, a fluid uptake rate of at least 2 micro-L/2, and a thickness between about 0.5 to 10mm. Therefore, it is a mere design choice and would be obvious to one of ordinary skill in the art at the time of the invention to modify the Webster/Nielsen device to have an absorption capacity between 30 and 10,000%, a fluid uptake rate of at least 2 micro-L/2, and a thickness between about 0.5 to 10mm.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster (US Patent 4,541,426) in view of Gilman et al. (US Patent 5,811,116). Webster substantially discloses the claimed invention; see rejection to claim 1 above. Webster fails to disclose a removable cover provided with projections into the apertures of the hydrogel sheet. However, Gilman discloses a patch (14) comprising a removable

Art Unit: 3772

cover (22) with projections that extend into the aperture (col. 4, lines 25-27). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Webster device with the removable cover, as taught by Gilman, in order to preserve the shape of the apertures before removal of the release cover.

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Silcock et al. (US Patent Application Publication), Chandra et al. (US Patent Application Publication 2003/0176827), Stickels et al. (US Patent 6,566,575), Hahnle et al. (US Patent 6,174,929), Chen et al. (US Patent 5,733,570), Hahnle et al. (US patent 6,136,873), Park et al. (US Patent 5,750,585), Mori et al. (US Patent 7,164,054).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon Jackson whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3772

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 10/19/07
Brandon Jackson
Examiner
Art Unit 3772

BLJ


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10/25/07